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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,271	09/10/2001	George M Yousef	MTS3USA	2550

270 7590 03/25/2003

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,271

Applicant(s)

YOUSEF ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,16,18,21,24,25,27 and 31-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,8,16,18,21,24,25,27 and 31-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1636

DETAILED ACTION

Claims 1, 8, 16, 18, 21, 24, 25, 27 and 31-45 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 27, 32, 33, 35-37, 39 and 44, drawn to an isolated nucleic acid of KLK gene, a vector comprising said nucleic acid, a host cell comprising said nucleic acid, a method of prepare a protein by culturing the host cell transformed with said vector and a composition comprising said nucleic acid.

Group II, claim(s) 8, 16 and 44, drawn to a KLK protein and a composition comprising said protein.

Group III, claims 18 and 38, drawn to an antibody of the KLK protein.

Group IV, claims 24 and 25, drawn to a method of detecting a nucleic acid molecule encoding a KLK protein by hybridization.

Group V, claim 31, drawn to a transgenic animal system for testing an agent reduces or inhibits a KLK protein associated pathology.

Group VI, claim 34, drawn to a regulatory sequence of the KLK gene fused to a nucleic acid encodes a heterologous protein.

Group VII, claims 21 and 40, drawn to a method of diagnosing and monitoring conditions mediated by a KLK protein by determining the presence of the nucleic acid encoding the protein or the protein itself.

Group VIII, claims 41 and 44, drawn to a method for identifying a substance that associates with a KLK protein by reacting the substance with the protein and a composition comprising said substance.

Art Unit: 1636

Group IX, claim 42 and 44, drawn to a method for evaluating a compound for its ability to modulate the biological activity of a KLK protein providing the protein with a substance associates with the protein and a test compound and a composition comprising said compound.

Group X, claim 43, drawn to a method of treating a condition mediated by a KLK protein by administering an antibody of the protein.

Group XI, claim 43, drawn to a method of treating a condition mediated by a KLK protein by administering a substance that associates with a KLK protein.

Group XII, claim 43, drawn to a method of treating a condition mediated by a KLK protein by administering a compound that modulates the biological activity of the KLK protein.

Group XIII, claim 45, drawn to a transgenic non-human mammal which does not express a KLK protein.

PCT Rule 13.2 requires that unity of the invention exists only when there is a shared same or corresponding technical feature among the claimed inventions. All the groupings are directed to a composition of KLK gene, protein or antibody, and different methods related to said gene protein or antibody but each group has a different special technical feature not shared by the remaining groups. Group I is directed to nucleic acids encoding a KLK protein, vector, host cell and method of making a KLK protein by culturing the host cell comprising said vector which has the special technical feature of a nucleic acid encoding the KLK protein, not shared by any of the remaining groups. Group II is directed to a KLK protein, such technical feature not shared by the remaining groups. Group III, V, VI and XIII are directed to an antibody, a transgenic animal system, a regulatory sequence and a transgenic knockout mammal which do not share special technical feature with each other and the remaining groups. Groups IV, VII-XII are drawn to different methods of diagnosing or treating a condition associated with KLK protein, evaluating compounds that modulate KLK protein, or identifying substance associated with KLK protein, which do not share a special technical feature with each other and the remaining groups.

Art Unit: 1636

Groups I-XIII are comprised of multiple inventions which are the products or methods drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. If any of Groups I-XIII are elected, applicants must elect a single invention which is the product or method drawn to one specific sequence (one SEQ ID NO and/or the corresponding KLK gene or protein encoded by the sequence) to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Application/Control Number: 09/936,271

Page 5

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
March 20, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER